IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

DOUGLAS L. SMITH and JANET BONAFEDE-SMITH, husband and wife,

Plaintiffs,

v. **No. CIV 98-558 BB/WWD**

AMERICAN HOME PRODUCTS CORPORATION,; WHITEHALL-ROBINS LABORATORIES, a Division of American Home Products; PERRIGO COMPANY; and PHARMACEUTICAL FORMULATIONS, INC.,

Defendants.

MEMORANDUM OPINION AND ORDER PARTIALLY GRANTING PLAINTIFFS' MOTION TO AMEND

THIS MATTER is before the Court on Plaintiffs 'motion seeking leave to file an amended complaint [#80]. The Court having considered the briefs of counsel and being otherwise informed, FINDS the Court having previously granted summary judgment on the strict liability count, amendment to restate

that claim would be fruitless, but the claim of intentional misrepresentation is an appropriate amendment under Federal Rule of Civil Procedure 15.

Discussion

Background

This case was filed in state court in April 1998 and removed to this Court shortly thereafter. In January 1999, Defendants filed their summary judgment motion package. This Court held hearings in September and October 1999 and granted Defendants summary judgment on Plaintiffs 'strict liability claim alleging that Defendants were required to warn the public of all known or knowable medical dangers of ibuprofen including those beyond the warnings expressly approved by the United States Food and Drug Administration ("FDA"). The Court, however, allowed Plaintiffs to seek leave to file an amended complaint to state claims based on their theory that Defendants withheld information or mislead the FDA in approving the prescribed warnings. Plaintiffs now seek leave to file an amended complaint with complaint attached.

The first problem with the amended complaint is that it is poorly drafted. The caption and paragraphs 6-8 appear intended to state claims against the very retailers who were originally named Defendants but dismissed in 1999. In their

reply, however, Plaintiffs acknowledge they "did not intend to assert claims against Retailers in their amended complaint and therefore, will agree to remove the Retailers from the caption and delete paragraphs six, seven and eight from the proposed amended complaint." (Pltfs' Combined Reply at 2).

First Cause of Action

As in the original complaint, Plaintiffs present the First Cause of Action under the rubric "Strict Liability" and again allege:

> **Defendants knew, or should have known in the exercise of reasonable care, that consumers without benefit of medical knowledge could not realize and could not detect the dangerous and harmful nature of Advil, Equate Ibuprofen and Wal-proven/Walgreens private label ibuprofen. Clear warnings which could reasonably be expected to catch the attention of a reasonably prudent person as to the dangers and side effects, in particular, the possibility of renal damage, should have been disseminated by labels, product inserts, information to physicians and media advertising to overcome the extensive advertising campaign proclaiming the safety and efficacy of these over-the-counter pain medications. Failure to warn rendered the product unreasonably dangerous.**

This was the very claim on which summary judgment was granted!

Plaintiffs' counsel, however, did understand a portion of the Court's ruling and would add a paragraph stating:

> **As a result of Defendants' manufacture, marketing, promotion, distribution and/or sale of this unreasonably dangerous over-the-counter drug and failure to report the known adverse effects to consumers and physicians, the FDA and/or its divisions, committees, and other governmental entitles as required by FDA regulation, FTC regulations and other statutes, the Plaintiff, DOUGLAS L. SMITH, was unreasonably exposed to the harmful side effects and damage caused by said drug and has suffered and will continue to suffer bodily harm, permanent injury, physical pain, emotional distress, lost wages, loss of enjoyment of life, extreme anxiety, continued worsening of his renal disease which resulted in renal failure requiring dialysis and a kidney transplant. Mr. Smith has incurred and will continue to incur expenses for medical care and anti-rejection drugs for the remainder of his life.**

Plaintiffs offer no law supporting the proposition that this should be a strict liability, as opposed to negligence, intentional misrepresentation or fraud-based, claim. Moreover, the social policy behind strict liability appears logically inconsistent with FDA labeling guidelines which allow only very minor changes without premarket approval. ***See*** **21 C.F.R. §§ 1.21; 201.57; 314.70; 47 Fed. Reg. at 54,756 (1982); 62 Fed. Reg. at 9026 (1997);** ***see also Chambers v. Osteonics Corp.*****, 109 F.3d 1243 (7th Cir. 1997).**

Given the fact the case has now been pending for two years and discovery is closed, and with the trial date rapidly approaching, the Court will not allow

Plaintiffs to assert the amended First Cause of Action as a strict liability claim. ***Chaveriat v. Williams Pipe Line Co.*****, 11 F.3d 1420 (7th Cir. 1993);** ***Henley v. FMC Corp.*****, 172 F.R.D. 193 (S.D. W. Va. 1997).**

Fifth Cause of Action

In the original complaint, Plaintiffs asserted a claim for intentional misrepresentation alleging Defendants falsely represented to the FDA and others that ibuprofen was "safe and efficacious." In the proposed amendment, Plaintiffs would add:

> **59. The Defendants had knowledge of the toxic effects of ibuprofen, the active ingredient of Advil, Equate Ibuprofen and Wal-proven/Walgreens private label ibuprofen as set forth and reported in the medical literature and other sources and continued, or should have continued to review and monitor medical literature and adverse reaction reports from the date such information became available to the present, but failed to take timely action or inform the FDA, FTC and other governmental entities to prevent the harm suffered by Douglas L. Smith.**
>
> **60. At the time the aforesaid representations were made, Defendants concealed from the medical profession, consumers, the FDA, its divisions and committees, the FTC, and other governmental entities, and in particular, Plaintiff, DOUGLAS L. SMITH, the toxic consequences related to the products use.**
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> *** * ***

> **62. At the time Defendants made the aforesaid representations to the regulatory agencies, and at the time Plaintiff, DOUGLAS L. SMITH consumed Advil, Equate Ibuprofen and Wal-profen/Walgreens private label ibuprofen, Plaintiff, physicians, the FDA, the FTC, and other governmental entitles were ignorant of the falsity of these representations and reasonably believed them to be true. In reliance upon Defendants' representations, approval was given for the product's sale, using labels approved by the FDA and advertising approved by the FTC, Plaintiff was induced to and did use and consume the products as herein described. If Plaintiff had known the actual facts, he would not have taken such action. The reliance of Plaintiff upon Defendants' representations was justified because they were made by individuals and entitles who appeared to be in a position to know the facts with approval by the appropriate governmental agencies.**

As was discussed at the previous hearings, many courts have recognized the Food, Drug and Cosmetic Act, 21 U.S.C. § 301-92 (1998), does not preempt a claim that the warnings required by the FDA were the result of fraud or misrepresentation. ***See, e.g., Stanton v. Astra Pharmaceutical Prods., Inc.,*** **718 F.2d 553 (3d Cir. 1983). Since this theory is a logical expansion of Plaintiffs' original claim for intentional misrepresentation, the amendment will be permitted.** ***Lowenschuss v. Kane,*** **520 F.2d 255 (2d Cir. 1975) (amendment permitted to state claim with greater specificity).**

O R D E R

Plaintiffs are GRANTED permission to file the amendment to their Fifth Cause of Action –Intentional Misrepresentation, but DENIED permission to file the amended First Cause of Action –Strict Liability.

Dated at Albuquerque this 19th day of April, 2000.

BRUCE D. BLACK
United States District Judge

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